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EXAMINER

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MARKUS HEHLI AND ALBERTO FERNANDEZ DELL'OCA

Appeal 2009-008160
Application 10/694,846
Technology Center 3700

Before JAMESON LEE, SALLY C. MEDLEY and
MICHAEL P. TIERNEY, *Administrative Patent Judges*.

Opinion for the Board filed by *Administrative Patent Judge* TIERNEY.

Opinion Dissenting filed by *Administrative Patent Judge* LEE.

TIERNEY, *Administrative Patent Judge*.

DECISION ON APPEAL¹

¹ The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, or for filing a request for rehearing, as recited in 37 C.F.R. § 41.52, begins to run from the “MAIL DATE” (paper delivery mode) or the “NOTIFICATION DATE” (electronic delivery mode) shown on the PTOL-90A cover letter attached to this decision.

A. STATEMENT OF THE CASE

This is a decision on appeal by the real party in interest, Synthes, Inc., under 35 U.S.C. § 134(a), from a final rejection of claims 1-18, the only claims on appeal. Appellant requests reversal of the Examiner's rejection of claims 1-18. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

Reference Relied on by the Examiner

Schmieding	U.S. 5,626,613	May 6, 1997
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The Rejections on Appeal

The Examiner provided the following grounds of rejection for the claims on appeal.

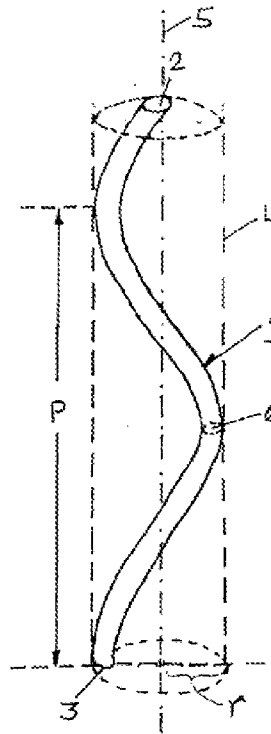
1. The Examiner rejected claims 1, 2, 7, 9, 13, 14, and 17 under 35 U.S.C. § 102(b) as being anticipated by Schmieding.
2. The Examiner rejected claims 3-6, 8, 10-12, 15-16 and 18 under 35 U.S.C. §103(a) as being unpatentable over Schmieding.

The Invention

The invention relates to an inside-the-bone support (intramedullary nail) used to repair long bone fractures. Claim 1 is reproduced below:

1. An osteosynthetic device comprising an intramedullary nail having a longitudinal shape with a central axis, a first end, and a second end, wherein the shape of the device is helical. (App. Br. 11, Claims App'x.).

Figure 1 is illustrative of the claimed invention and is reproduced below:



Appellant's Fig. 1 depicts an intramedullary nail according to the invention.

B. ISSUE

1. Did the Examiner err in determining that the claimed intramedullary nail structure is anticipated by Schmieding's cork-screw bone anchor?
2. Did the Examiner err in determining that one of ordinary skill in the art had reason to form a nail with various shapes, such as a square?

C. FINDINGS OF FACT

1. Schmieding describes a suture anchor that is to be inserted into, and locked within, a bone. (Col. 4, ll. 7-8).

2. Schmieding's suture anchor is a helical body having the shape of a clockwise helix with a hollow central core. (Col. 3, ll. 13-14).

3. Figure 1 of Schmieding depicts a representative suture anchor:

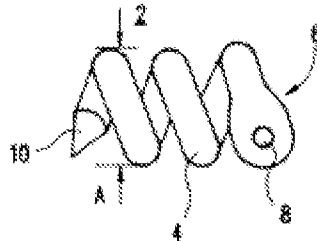


FIG. 1

Schmieding's Fig. 1 depicts a corkscrew suture anchor.

4. Schmieding's suture anchor has a central axis around which the suture anchor may be driven into the bone. (Fig. 1 and col. 4, ll. 42-46).

5. Schmieding's helical body contains first and second ends. (Fig. 1 and col. 3, ll. 18-19 and 22-23).

6. Schmieding describes its suture anchor as formed of a resilient material. (Col. 3, l. 64).

7. Schmieding teaches that the helical suture anchors can be made in a variety of sizes and shapes. (Col. 3, ll. 25-26).

D. PRINCIPLES OF LAW

An apparatus claim is not patentable over prior art where the claimed structure is that of the prior art. *Catalina Mktg Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 809 (Fed. Cir. 2002). Furthermore, “[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 416 (2007).

E. ANALYSIS

As to the anticipation rejection, Appellant contends that independent claim 1 is allowable over the art, and as a result, dependent claims 2, 7, 9, 13, 14 and 17 are likewise allowable. As to the obviousness rejection, Appellant separately argues dependent claims 3-6, 11 and 15-16 (group I), and dependent claims 8, 10 and 12 (group II) while contending that dependent claim 18 stands with claim 1. For purposes of this appeal, we analyze claims 1, 3 and 8. *See* 37 C.F.R. § 41.37(c)(1)(vii).

1. *Schmieding Describes the Structure of Appellant Claim 1*

Appellant disagrees with the Examiner’s anticipation determination and contends that Schmieding does not teach an intramedullary nail. (App. Br. 4-6, Reply Br. 2-4). In particular, Appellant contends that the term “intramedullary nail” is clearly recognized by those skilled in the art as requiring certain structural characteristics such as biocompatibility and having enough strength to absorb the stresses to which the bone will be exposed. Appellant contends that these characteristics are not taught by Schmieding’s suture anchor. (App. Br. 4-5 and Reply Br. 3-4). Even accepting Appellant’s claim construction for this term, we find that

Schmieding teaches these structural characteristics. Specifically, Schmieding teaches biocompatibility. (Col. 3, l. 15). Schmieding also discloses suture anchors that are locked within the bone and which can absorb stresses that normally would be applied directly to the bone. (Col. 2, ll. 37-45).

Additionally, Appellant contends that Schmieding's corkscrew anchor is not a nail and that Schmieding's anchor is not suitable for insertion into the medullary canal of a bone and hence is not an "intermedullary nail." (App. Br. 5-6, Reply Br. 4). Appellant however, consistently states that the claimed intramedullary nail is helical in structure but does not identify how that claimed helical structure differs from the corkscrew structure of Schmieding. Specifically, Schmieding describes the positively recited structure of claim 1: a nail having a longitudinal shape with a central axis with a first and second end where the nail is helical in shape and can be used in the treatment of bones. Furthermore, Appellant's contention that the structure of Schmieding is not suitable for insertion into the medullary canal is not supported by any evidence of record. (App. Br. 14, Evidence App'x, "No evidence has been entered or relied upon in the present appeal"). Appellant's unsupported attorney argument does not take the place of evidence in the record. *Estee Lauder, Inc. v. L'Oreal, S.A.*, 129 F.3d 588, 595 (Fed. Cir. 1997). In view of the fact that the patentability of an apparatus claim depends on the claimed structure and not on the use or purpose of that structure (*see Catalina*, 289 F.3d at 809), we find that Schmieding's suture anchor anticipates the claimed device.

2. *Schmieding Makes the Structure of Claim 3 Obvious.*

Claim 3 includes all the limitations of claim 1 and further specifies that the helix has a rotation of less than 540°. (App. Br. 11, Claims App'x.).

The Examiner contends that while Schmieding does not explicitly teach a rotation of less than 540°, it would have been obvious to one skilled in the art to employ such angles given Schmieding's teachings. Appellant however, argues that having a rotation of less than 540° for Schmieding's anchor fails to take into account the impact these rotational angles would have on Schmieding's suture anchor. Although Appellant argues that the change is likely to reduce the degree the suture anchor would be inserted into the bone, Appellant does not identify the specific impact the angles would have on or present evidence demonstrating the criticality of this rotational angle. Schmieding teaches the structural relationship that wire size increases as the amount of rotation decreases. (Col. 3, ll. 56-58).

Schmieding further teaches that those skilled in the art may make modifications to the specifically described and depicted anchors. (Col. 5, ll. 5-7). As Schmieding describes the general conditions of the helical nail and as Appellant has not demonstrated the criticality of the rotational limitation, we hold that the Examiner did not err with respect to claim 3. *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1351 (Fed. Cir. 2008) (A claim is obvious where the claimed parameters were well-known and only routine experimentation by one of ordinary skill in the art would have been necessary).

3. *Schmieding Makes the Structure of Claim 8 Obvious*

Claim 8 includes all the limitations of claim 1 and further specifies that the cross-sectional shape orthogonal to the central axis of Appellant's helix is a square or a star. (App. Br. 11, Claims App'x.).

Appellant contends that the Examiner does not take into account the impact such a shape, e.g., a square or a star, would have on the function of Schmieding's suture anchor and that there is no motivation to modify the cross-sectional shape of Schmieding. Again, Appellant does not identify the criticality of these limitations or present evidence in support of its contention.

A person of ordinary skill in the art is well aware that nails come in different cross sectional shapes and sizes and Schmieding specifically contemplates varying the size and shape of its anchor. (Col. 3, ll. 25-26). A person skilled in the art is also a person of ordinary creativity, not an automaton. *KSR*, 550 U.S. at 421. Thus, we hold that modifying the shape of Schmieding's anchor, as claimed, would have been obvious to one of ordinary skill in the art, as Schmieding specifically teaches one skilled in the art to vary the shape and size of the anchor and that also, it would have been obvious to one of ordinary skill in the art to identify workable shapes, e.g., a square, through routine experimentation.

F. CONCLUSIONS OF LAW

1. Claims 1, 2, 7, 9, 13, 14, and 17 are anticipated by Schmieding's corkscrew bone anchor.
2. One of ordinary skill in the art had reason to form a nail with the shapes specified in claims 3-6, 8, 10-12, 15-16 and 18.

G. ORDER

The rejections of claims 1-18 under 35 U.S.C. §§ 102(b) and 103(a) as unpatentable over Schmieding, is affirmed.

No time period for taking any subsequent action in connection with the appeal may be extended under 37 C.F.R. §1.136(a).

LEE, Administrative Patent Judge. Dissenting.

I agree with the Appellant that the Examiner has not shown that the suture anchor of Schmieding would be regarded by one with ordinary skill in the art as an intramedullary nail. An intramedullary nail is for insertion into a long bone to support it in sharing the load carried by the bone. Structurally, it has to be sufficiently long and strong enough to serve the normal uses of an intramedullary nail. The Examiner has established neither of those qualities in Schmieding's suture anchor.

The portion of Schmieding cited by the majority as disclosing that the suture anchor is sufficiently strong to absorb the stresses normally sustained by the bone makes no such disclosure. It refers to "pullout strength" which has to do with the anchor's resisting being pulled out of the bone. That is no indication that the structure is strong enough to be effective in sharing the load carried by the bone in order to help support the bone. In that regard, note also that Schmieding discloses that the suture anchor is made of resilient material. (Schmieding col. 3, ll. 63-64). It also appears that the suture anchor is not sufficiently long to support a long bone, even if it is inserted into an intramedullary channel.

The Examiner has not made out a reasonable case that Schmieding's suture anchor would work as an intramedullary nail or that one with ordinary skill in the art would recognize Schmieding's suture anchor as an intramedullary nail. I would reverse the rejection of all claims.

Appeal 2009-008160
Application 10/694,846

bim

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